UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,769	09/05/2003	Brian Varnum	01-1554-F	8860

20306 7590 10/11/2005

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER	
RINAUDO, JO ANN S	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,769	VARNUM ET AL.	
	Examiner	Art Unit	
	Jo Ann Rinaudo	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *3,4,6-9,12-31,39,41,43,45,60 and 61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,10,11,32-38,40,42,44 and 46-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-61 are pending.

2. Applicant's election with traverse of Group III (Claims 5, 10, 11, 32-38, 40, and 55-59) in the reply filed on 08/02/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 1, 2, 5, 10, 11, 32-38, 40, 42, 44, and 46-59 are under consideration as they are drawn to an isolated human antibody that binds to interleukin-1 receptor type 1 (IL-1R1), with a heavy chain variable SEQ ID NO: 16; SEQ ID NO: 63 (heavy chain CDR1), SEQ ID NO: 66 (heavy chain CDR2), SEQ ID NO: 69 (heavy chain CDR3); a light chain variable SEQ ID NO: 18; SEQ ID NO: 71 (light chain CDR1), SEQ ID NO: 73 (light chain CDR2), and SEQ ID NO: 75 (light chain CDR3); an isolated human antibody that binds to SEQ ID NO:76; and a pharmaceutical composition containing the antibody. Claims 46-54 are included because they read on the antibodies recited in elected Group III.

4. Claims 3, 4, 6-9, 12-31, 39, 41, 43, 45, 60, and 61 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions.

5. SEQ ID NO: 75 is recited in Claim 46 as human light chain CDR3 region and in Claim 53 as human heavy chain CDR2 region. SEQ ID NO: 73 is recited in Claim 47 as human light chain CDR2 region and in Claim 54 as human heavy chain CDR3 region. The specification on page 12, lines 3-14, disclose SEQ ID NO: 75 as the human light chain CDR1 and SEQ ID NO: 73 as the human light chain CDR2. Correction of the claims is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 2, 5, 10, 11, 32-38, 40, 42, 44, 46-54, and 56-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1); with heavy chain variable region of SEQ ID NO:16 and a light chain variable region of SEQ ID NO:18, or an antigen binding fragment thereof; or an antibody consisting of 6 CDR's, with the heavy chain 3 CDR regions consisting of SEQ ID NO: 63 (heavy chain CDR1), SEQ ID NO: 66 (heavy chain CDR2); SEQ ID NO: 69 (heavy chain CDR3) and the light chain 3 CDR regions consisting of SEQ ID NO: 71 (light chain CDR1); SEQ ID NO: 73 (light chain CDR2); SEQ ID NO: 75 (light chain CDR3); and an isolated human antibody that binds to SEQ ID NO:76 *does not reasonably provide enablement for* an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1), or an immunologically functional immunoglobulin fragment thereof, with the heavy chain SEQ ID NO:16 (Claims 1, 32-38, 40, and 42); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) , or an immunologically functional immunoglobulin fragment thereof, with the light chain SEQ ID NO:18 (Claims 2, 32-38, 40 and 44); an isolated human antibody with a human heavy chain CDR3 region SEQ ID NO:69 and a human light chain CDR3 region SEQ ID NO:75 (Claim 46); an isolated human antibody with a human heavy chain CDR2 region SEQ ID NO:66 and a human light chain CDR2 region SEQ ID NO:73 (Claim 47); an isolated human antibody with a human heavy chain CDR1 region SEQ ID NO:63 and a human light chain CDR1 region SEQ ID NO:71 (Claim 48); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) with a human heavy chain CDR1 region SEQ ID NO:63 (Claim 49); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) with a human heavy chain CDR2 region SEQ ID NO:66 (Claim 50); an isolated human antibody that specifically binds to

interleukin-1 receptor type 1 (IL-1R1) with a human heavy chain CDR3 region SEQ ID NO:69 (Claim 51); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) with a human light chain CDR1 region SEQ ID NO:71 (Claim 52); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) with a human light chain CDR2 region SEQ ID NO:73 (Claim 53); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) with a human light chain CDR3 region SEQ ID NO:75 (Claim 54); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) with at least a 90% sequence identity to heavy chain SEQ ID NO:16 and with at least a 90% sequence identity to light chain SEQ ID NO:18 (Claim 11); an antibody that specifically binds Epitope 4 of IL-1R1 (Claim 56); an immunologically functional immunoglobulin fragment thereof, of an IgG2 antibody with the heavy chain SEQ ID NO:16 and a light chain SEQ ID NO:18 (Claim 57); an immunologically functional immunoglobulin fragment thereof, of an antibody which binds specifically to the polypeptide of SEQ ID NO: 76 (Claim 58); and an immunologically functional immunoglobulin fragment thereof, of an antibody which binds specifically to to Epitope 4 of IL-1R1 (Claim 59). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/or use the invention commensurate in scope with these claims.

8. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, and the amount of experimentation required to enable one skilled in the art to practice the invention.

9. Janeway et al. teach that antibody binding and specificity require a heavy and light chain and each chain contains 3 CDR's, for a total of 6 CDR's in an intact antibody. The claims recite only the heavy chain sequence (Claims 1, 32-38, 40, and 42); only the specific CDR3 combination of the heavy and light chain (Claim 46); only the specific

CDR2 combination of the heavy and light chain (Claim 47); only the specific CDR1 combination of the heavy and light chain (Claim 48); only the specific CDR3 region (Claim 49) for the heavy chain; only the specific CDR2 region (Claim 50) for the heavy chain; and only the specific CDR1 region (Claim 51) for the heavy chain. The claims do not provide guidance for making a complete antibody specific for interleukin-1 receptor type 1 (IL-1R1). Any light chain can be associated with the heavy chain sequences to form an antibody molecule, and the recited CDR sequences can be combined with any other CDR sequences to form the 6 CDR regions involved in antigen binding, thus the antibody formed would not reasonably be expected to have specificity for human interleukin-1 receptor type 1 (IL-1R1). Therefore, the lack of guidance provided and the amount of experimentation required does not enable one skilled in the art to make or use an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) as recited in the claims.

10. Janeway et al. teach that antibody binding and specificity require a heavy and light chain and each chain contains 3 CDR's, for a total of 6 CDR's in an intact antibody. Further, the claims recite only the light chain sequence (Claims 2, 32-38, 40, and 44); only the specific CDR3 combination of the heavy and light chain (Claim 46); only the specific CDR2 combination of the heavy and light chain (Claim 47); only the specific CDR1 combination of the heavy and light chain (Claim 48); only the specific CDR3 region (Claim 52) for the light chain; only the specific CDR2 region (Claim 53) for the light chain; and only the specific CDR1 region (Claim 54) for the light chain. The claims do not provide guidance for making a complete antibody specific for interleukin-1 receptor type 1 (IL-1R1). Any heavy chain can be associated with the light chain sequence to form an antibody molecule, and the recited CDR sequences can be combined with any other CDR sequences to form the 6 CDR regions involved in antigen binding, thus the antibody formed would not reasonably be expected to have specificity for human interleukin-1 receptor type 1 (IL-1R1). Therefore, the lack of guidance provided and the amount of experimentation required does not enable one skilled in the

art to make or use an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) as recited in the claims.

11. The term "immunologically functional immunoglobulin fragment" encompasses the broad functions of an immunoglobulin molecule (Claims 1, 2, 5, 10, 32-38, 40, 42, 44, and 57-59). The specification provides no examples of antibodies, upon which the skilled artisan could rely upon for making an "immunologically functional immunoglobulin fragment". The specification discloses "immunologically functional immunoglobulin fragment" as "a polypeptide fragment that contains at least the variable domains of the immunoglobulin heavy and light chains" (see p.17, lines 27-29, in particular). Given the well known high degree of polymorphism of antibodies (see Abbas et al. p. 144, column 2, paragraph 2), the skilled artisan could not make the claimed "immunologically functional immunoglobulin fragment" in the absence of the appropriate starting materials in order to practice the claimed invention or provide the appropriate correlation between the structure and function of the "immunologically functional immunoglobulin fragment". It is well established in the art that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody. Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al. (see entire document and page 1980 column 1, lines 28-52 and column 2, lines 1-38, in particular). Therefore, the lack of guidance provided, the lack of sufficient working examples, and the amount of experimentation required does not enable one skilled in the art to make and use an "immunologically functional immunoglobulin fragment".

12. Claim 11 recites an antibody with "at least 90% sequence identity". The specification discloses only a single heavy chain variable sequence (SEQ ID NO:16) and only a single light chain variable sequence (SEQ ID NO:18) to an isolated human antibody that specifically binds interleukin-1 receptor type 1 (IL-1R1). Claim 11 encompasses in its breadth *any* heavy chain variable sequence with "at least 90%

sequence identity" to the amino acid sequence in SEQ ID NO:16; and *any* light chain variable sequence with "at least 90% sequence identity" to the amino acid sequence in SEQ ID NO:18. The specification provides no examples of antibodies, upon which the skilled artisan could rely upon for making a heavy chain variable sequence with "at least 90% sequence identity" to the amino acid sequence in SEQ ID NO:16; and a light chain variable sequence with "at least 90% sequence identity" to the amino acid sequence in SEQ ID NO:18. It is well established in the art that even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al. (see entire document and page 1980 column 1, lines 28-52 and column 2, lines 1-38, in particular). Thus the recitation of percent identity language, in the absence of *a testable function* and limitations regarding the *sequence length over which the percent identity is required*; does not allow the skilled artisan to make and use the encoding nucleic acids commensurate in scope with the instant claims without undue experimentation.

13. Claims 56, and 59 encompass an antibody which binds specifically to Epitope 4 of IL-1R1. The specification discloses that Epitope 4 is only three amino acids, YSV (see page 9, lines 21-23, in particular). Harlow et al. teach that six residues are the smallest synthetic peptides that elicit an antibody response and that smaller peptides are weak and will not recognize the protein of interest (see page 76, *Size of the Peptide*, in particular). Therefore, the lack of guidance provided, the lack of sufficient working examples, and the amount of experimentation required does not enable one skilled in the art to make and use an antibody which binds specifically to Epitope 4 of IL-1R1.

14. Reasonable correlation must exist between the claims and the enablement set forth. Without sufficient guidance, knowing only the heavy chain sequence or only the light chain sequence of an antibody results in unpredictable binding specificity of the antibody molecule; thus the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

15. Claims 1, 2, 5, 10, 11, 32-38, 40, 42, 44, 46-54, and 56-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonable convey to one skilled in the art that the inventor(s), at the time of the application was filed, had possession of the claimed invention.

16. Applicant is in possession of an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1); with heavy chain variable region of SEQ ID NO:16 and a light chain variable region of SEQ ID NO:18, or an antigen binding fragment thereof; or an antibody consisting of 6 CDR's, with the heavy chain 3 CDR regions consisting of SEQ ID NO: 63 (heavy chain CDR1), SEQ ID NO: 66 (heavy chain CDR2); SEQ ID NO: 69 (heavy chain CDR3) and the light chain 3 CDR regions consisting of SEQ ID NO: 71 (light chain CDR1); SEQ ID NO: 73 (light chain CDR2); SEQ ID NO: 75 (light chain CDR3); and an isolated human antibody that binds to SEQ ID NO:76. Applicant is not in possession of an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1), or an immunologically functional immunoglobulin fragment thereof, with the heavy chain SEQ ID NO:16 (Claims 1, 32-38, 40, and 42); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) , or an immunologically functional immunoglobulin fragment thereof, with the light chain SEQ ID NO:18 (Claims 2, 32-38, 40 and 44); an isolated human antibody with a human heavy chain CDR3 region SEQ ID NO:69 and a human light chain CDR2 region SEQ ID NO:75 (Claim 46); an isolated human antibody with a human heavy chain CDR2 region SEQ ID NO:66 and a human light chain CDR2 region SEQ ID NO:73 (Claim 47); an isolated human antibody with a human heavy chain CDR1 region SEQ ID NO:63 and a human light chain CDR1 region SEQ ID NO:71 (Claim 48); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) with a human heavy chain CDR1 region SEQ ID NO:63 (Claim 49); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) with a human heavy chain CDR2 region SEQ ID NO:66 (Claim 50); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) with a human heavy chain

CDR3 region SEQ ID NO:69 (Claim 51); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) with a human light chain CDR1 region SEQ ID NO:71 (Claim 52); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) with a human light chain CDR2 region SEQ ID NO:73 (Claim 53); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) with a human light chain CDR3 region SEQ ID NO:75 (Claim 54); an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) with at least a 90% sequence identity to heavy chain SEQ ID NO:16 and with at least a 90% sequence identity to light chain SEQ ID NO:18 (Claim 11); an antibody that specifically binds Epitope 4 of IL-1R1 (Claim 56); an immunologically functional immunoglobulin fragment thereof, of an IgG2 antibody with the heavy chain SEQ ID NO:16 and a light chain SEQ ID NO:18 (Claim 57); an immunologically functional immunoglobulin fragment thereof, of an antibody which binds specifically to the polypeptide of SEQ ID NO: 76 (Claim 58); and an immunologically functional immunoglobulin fragment thereof, of an antibody which binds specifically to to Epitope 4 of IL-1R1 (Claim 59).

17. The claims recite only the heavy chain sequence (Claims 1, 32-38, 40, and 42); only one of the specific CDR regions of the heavy and light chain combinations (Claims 46-48); and only the specific CDR3 region (Claim 49), CDR2 region (Claim 50), and CDR1 region (Claim 51) for the heavy chain comprising an isolated human antibody that specifically binds interleukin-1 receptor type 1 (IL-1R1). Further, only the light chain sequence is recited in Claims 2, 32-38, 40, and 44; only one of the specific CDR regions of the heavy and light chain combinations (Claims 46-48); and only the specific CDR3 region (Claim 52), CDR2 region (Claim 53), and CDR1 region (Claim 54) for the light chain comprising an isolated human antibody that specifically binds interleukin-1 receptor type 1 (IL-1R1). Broadly claiming an antibody by only reciting the heavy chain or only the light chain, or only the specific combination of heavy and light chain for the CDR1, 2 or 3 CDR regions, or only one of the 6 specific CDR regions of the heavy or light chain, the applicant has not described the structural characteristics of the intact

immunoglobulin molecule. An intact immunoglobulin molecule contains both a heavy and light chain, which each have three CDR regions. The intact immunoglobulin molecule requires the heavy and light chain CDR regions for antigen binding and specificity.

18. The specification provides the sequences associated with the three CDR regions of the light chain. The claims do not disclose sequence of the heavy chain variable region associated with the light chain variable region. Thus, any heavy chain can be paired with the light chain variable region recited in the claims. Therefore, the skilled artisan cannot envision all the contemplated heavy chain possibilities recited in the instant claims.

19. There is insufficient written description of an "immunologically functional immunoglobulin fragment thereof" (Claims 1, 2, 5, 10, 32-38, 40, 42, 44, and 57-59); an antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1) with at least a 90% sequence identity to heavy chain SEQ ID NO:16 and with at least a 90% sequence identity to light chain SEQ ID NO:18 (Claim 11); and an antibody that specifically binds Epitope 4 of IL-1R1 (Claims 56 and 59). The specification does not provide sufficient structural and functional characteristics coupled with a known or disclosed correlation between function and structure (see page 17, lines 27-29; page 9, lines 21-23 and page 7, lines 17-25, in particular). The specification has only disclosed an isolated human antibody that specifically binds to interleukin-1 receptor type 1 (IL-1R1); with heavy chain variable region SEQ ID NO:16 and light chain variable region SEQ ID NO:18, or an antigen-binding fragment. Therefore the skilled artisan cannot envision all the contemplated immunologically functional immunoglobulin fragments, antibodies with at least a 90% sequence identity to heavy chain SEQ ID NO:16 and with at least a 90% sequence identity to light chain SEQ ID NO:18; and an antibody that specifically binds Epitope 4 of IL-1R1.

20. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred,

regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

21. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

22. Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> *(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a*

patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

24. Claims 55 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,511,665.

25. The '665 patent teaches human antibodies to the IL-1 receptor with the amino acid sequence as described in Figures 5A-C (see column 2, lines 64-66, in particular). The '665 patent also teaches that truncated or soluble forms of the IL-1 receptor can be used for the production of antibodies (see column 5, lines 27-36 and column 27, lines 9-22, in particular). The amino acid sequence in Figures 5A-C encompasses the polypeptide of SEQ ID NO:76 of the instant application. Therefore the prior teachings anticipate the claimed invention.

26. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

27. No claim is allowed.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jo Ann Rinaudo whose telephone number is 571.272.8143. The examiner can normally be reached on M-F, 8:30AM - 5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571.272.0841. The fax phone number for the organization where this application or proceeding is assigned is 571.273.8300.

29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jo Ann Rinaudo, Ph.D.
Patent Examiner
9/26/2005

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600